



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2022-0940; FRL-10871-01-OCSP]

Aspergillus Flavus Strain AF36; Amendment to an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing tolerance exemption for residues of *Aspergillus flavus* strain AF36 by establishing an exemption for use on all food and feed commodities of cotton, corn, pistachio, almond, and fig when used in accordance with label directions and good agricultural practices. Interregional Research Project Number 4 (IR-4) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting to amend the existing tolerance exemption for *Aspergillus flavus* strain AF36. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* strain AF36 under FFDCA when used in accordance with the amended tolerance exemption.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0940, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave. NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Frank Ellis, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1400; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file

your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2022-0940 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although EPA strongly encourages those interested in submitting objections or a hearing request to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf. At this time, because of the COVID-19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal delivery, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system at https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf.

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, *e.g.*, the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564-6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental

Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2022-0940, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Background

In the *Federal Register* of January 3, 2023, (88 FR 38) (FRL-9410-08), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 2E8988) by IR-4, North Carolina State University, 1730 Varsity Drive, Suite 210, Venture IV, Raleigh, NC 27606 on behalf of the Arizona Cotton Research and Protection Council, 3721 East Wier Avenue, Phoenix, AZ 85040. The petition requested that 40 CFR 180.1206 be amended to establish an amendment/expansion of the existing tolerance exemption for the microbial pesticide *Aspergillus flavus* strain AF36 to include

use on all food and feed commodities of cotton, corn, pistachio, almond, and fig. That document referenced a summary of the petition prepared by the petitioner IR-4 and available in the docket via <https://www.regulations.gov>. EPA received no comments in response to the notice of filing.

EPA changed the active ingredient name in the amended tolerance exemption expression from “*Aspergillus flavus* AF36” to “*Aspergillus flavus* strain AF36.” In addition, EPA consolidated the crops into one paragraph; condensed the list of cotton crops by changing the expression from “cotton, gin byproducts; cotton, hulls; cotton, meal; cotton, refined oil; cotton, undelinted seed” to “all food and feed commodities of cotton”; condensed the list of corn crops by changing the expression from “corn, field, forage; corn, field, grain; corn, field, stover; corn, field, aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover” to “[all food and feed commodities of] corn, field; corn, sweet; corn, pop”; and removed the stipulation “when applied/used as an antifungal agent.” EPA is also revoking the section 18 emergency exemption for residues of *Aspergillus flavus* strain AF36 in or on dried figs that expired on December 31, 2017. The reasons for these changes are explained in Unit III.C.

III. Final Rule

A. EPA’s Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C),

which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicological and exposure data on *Aspergillus flavus* strain AF36 and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the documents entitled “Comprehensive Science Review: New Food Uses for a New End Use Product (EP) *Aspergillus flavus* AF36 Prime (71693-G) containing an unregistered source of the active ingredient *Aspergillus flavus* strain AF36 and a petition to amend an existing tolerance exemption (40 CFR 180.1206) to include all food and feed commodities of any included crops” (Human Health Risk Assessment for New Food Use of *Aspergillus flavus* strain AF36) and “Addendum to Comprehensive Science Review: New Food Uses for a New End Use Product (EP) *Aspergillus flavus* AF36 Prime (71693-G) containing an unregistered source of the active ingredient *Aspergillus flavus* strain AF36 and a petition to amend an existing tolerance exemption (40 CFR 180.1206) to include all food and feed commodities of any included crops.” These documents, as well as other relevant information, are available in the docket for this action as described under

ADDRESSES.

The toxicological profile of *Aspergillus flavus* strain AF36 was previously described in the “Biopesticides Registration Action Document *Aspergillus flavus* AF36,” available in docket EPA-HQ-OPP-2003-0323, and “*Aspergillus flavus* Interim Registration Review Decision Case Number 6008,” available in docket EPA-HQ-OPP-2015-0281. The toxicological profile remains

unchanged, and the available data demonstrated that, with regard to humans, *Aspergillus flavus* strain AF36 is not toxic, pathogenic, or infective via the oral or inhalation routes. The data requirement for acute intravenous toxicity/pathogenicity was met with scientific rationale based on acute oral toxicity and acute pulmonary toxicity/pathogenicity data, which indicated that test animals' immune systems were intact and able to process and clear *Aspergillus flavus* strain AF36. Although there is potential for dietary and non-occupational exposure to residues of *Aspergillus flavus* strain AF36, there is not a concern due to the lack of potential for adverse effects. Because there are no threshold levels of concern with the toxicity, pathogenicity, or infectivity of *Aspergillus flavus* strain AF36, EPA determined that no additional margin of safety is necessary to protect infants and children as part of the qualitative assessment conducted.

Based upon its evaluation in the Human Health Risk Assessment for New Food Use of *Aspergillus flavus* strain AF36, which concludes that there are no risks of concern from aggregate exposure to *Aspergillus flavus* strain AF36, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Aspergillus flavus* strain AF36.

B. Analytical Enforcement Methodology

An analytical method is not required for *Aspergillus flavus* strain AF36 because EPA is amending an exemption from the requirement of a tolerance without any numerical limitation.

C. Revisions to the Requested Amendment to a Tolerance Exemption

Four non-substantive modifications were made to the requested tolerance exemption that do not impact the safety finding for *Aspergillus flavus* strain AF36. EPA changed the active ingredient name from “*Aspergillus flavus* AF36” to “*Aspergillus flavus* strain AF36” to align with current active ingredient naming conventions. EPA consolidated the crops into one paragraph that includes “all food and feed commodities of almond; corn, field; corn, pop; corn, sweet; cotton; fig; and pistachio” because the requested amendment to the tolerance exemption proposes to add “all food and feed commodities” for each crop in the tolerance exemption. The

Agency's change creates a more concise list that covers all crops petitioned for by the petitioner and aligns with the Agency's food and feed commodity vocabulary. EPA removed the stipulation for the exemption from the requirement of a tolerance for residues of *Aspergillus flavus* strain AF36 "when applied as an antifungal agent," as the specification "when used in accordance with label directions and good agricultural practices" adequately addresses the Agency's safety concerns with the application methods. As a housekeeping matter, EPA also removed the section 18 emergency exemption for residues of *Aspergillus flavus* strain AF36 in or on dried figs because it expired on December 31, 2017.

D. Conclusion

Therefore, the existing *Aspergillus flavus* strain AF36 tolerance exemption is amended by establishing a tolerance exemption for residues of the microbial pesticide *Aspergillus flavus* strain AF36 in or on all food and feed commodities of almond; corn, field; corn, pop; corn, sweet; cotton; fig; and pistachio when used in accordance with label directions and good agricultural practices.

IV. Statutory and Executive Order Reviews

This action amends a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority

Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are amended on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 28, 2023.

Frank Ellis,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL
RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.1206 to read as follows:

§180.1206 *Aspergillus flavus* strain AF36; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide *Aspergillus flavus* strain AF36 in or on all food and feed commodities of almond; corn, field; corn, pop; corn, sweet; cotton; fig; and pistachio when used in accordance with label directions and good agricultural practices.

[FR Doc. 2023-09732 Filed: 5/5/2023 8:45 am; Publication Date: 5/8/2023]